**UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

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| NEW MEXICO UNITED FOOD AND COMMERCIAL WORKERS UNION'S AND EMPLOYERS' HEALTH AND WELFARE TRUST FUND, on behalf of itself and all others similarly situated,<br>Plaintiff,<br><br>v.<br><br>PURDUE PHARMA L.P., et al.,<br><br>Defendants. | ** | **Civil Action No. 07-cv-6916-JGK** |

**THE PURDUE DEFENDANTS' MEMORANDUM**
**IN SUPPORT OF THEIR MOTION FOR JUDGMENT ON THE PLEADINGS**

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The Purdue Defendants[1] ("Purdue") respectfully submit this Memorandum in support of their Motion for Judgment on the Pleadings pursuant to Fed. R. Civ. P. 12(c).

## INTRODUCTION

On August 1, 2007, New Mexico United Food and Commercial Workers Union's and Employers' Health and Welfare Trust Fund ("Plaintiff") filed this case against Purdue and various other defendants. Plaintiff seeks to recover the payments it made to reimburse its members for their purchases of OxyContin® Tablets ("OxyContin") – even though ***Plaintiff continues to this day to reimburse its members for such purchases***. (Compl. ¶ 3.) Plaintiff's claims rely on an abstract and hypothetical injury theory and a highly attenuated chain of causation. According to Plaintiffs: (1) Purdue misrepresented the risks and efficacy of OxyContin to *doctors* and *consumers* (but *not* to *Plaintiff*) (*e.g.*, *id.* ¶¶ 29-31, 33, 36, 58-59); (2) doctors responded by prescribing more OxyContin than they otherwise would have (*e.g.*, *id.* ¶¶ 39-40); (3) consumers responded by obtaining and purchasing more prescriptions for OxyContin than they otherwise would have (*e.g.*, *id.* ¶¶ 36-38); (4) Purdue thereby increased its "market penetration of OxyContin" and was able to "charge more for OxyContin than it otherwise would have been able to charge" (*id.* ¶ 38); and, as a result, (5) Plaintiff paid "substantial amounts of money for the artificially high costs of filling OxyContin prescriptions" (*id.* ¶ 75).

Plaintiff insists that it is entitled to recover many millions of dollars under RICO, state consumer fraud statutes, and the equitable doctrine of "unjust enrichment" – and it purports to sue on behalf of a nationwide class of third-party payors ("TPPs"). Notably, Plaintiff does not allege that *but for the alleged misrepresentations, it would have excluded OxyContin from the list of medications for which Plaintiff reimburses its insureds (its "formulary") or would otherwise*

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[1] The Purdue Defendants are Purdue Pharma L.P., Purdue Pharma, Inc., The Purdue Frederick Company, Inc. (d/b/a The Purdue Frederick Company) and P.F. Laboratories, Inc.

*have treated OxyContin any differently than it did.* To the contrary, not only does Plaintiff concede that it continues to make payments for OxyContin, it does not allege that it changed the medication's formulary status or otherwise discouraged its members from using the medication since learning the "truth" about the alleged misrepresentations at issue here. Plaintiff alleges only that Purdue's fraud impacted the behavior of doctors and consumers which, in turn, "artificially inflated" the costs Plaintiff incurred reimbursing its members for OxyContin. Such a "fraud on the market" theory is unsustainable for the following independently sufficient reasons:

***First***, Plaintiff lacks Article III standing to assert any of its claims. A "fraud-on-the-market" theory cannot establish the requisite injury-in-fact where, as here, the plaintiff "*continue[s] to purchase [the drug] even though they are purportedly now aware of the 'truth' regarding its alleged lack of [the touted] benefits.*" *Prohias v. Pfizer, Inc.*, 485 F. Supp. 2d 1329, 1335 (S.D. Fla. 2007) (emphasis added). This case thus stands in sharp contrast to *Desiano v. Warner-Lambert Co.*, 326 F.3d 339, 344 (2d Cir. 2003), where the drug at issue had been withdrawn from the market and the plaintiffs stopped making payments for it after learning of the alleged misrepresentations.

Moreover, Plaintiff has failed to establish the requisite causal nexus because it has not alleged an "injury fairly traceable to [Purdue's] allegedly unlawful conduct." *Allen v. Wright*, 468 U.S. 737, 751 (1984). Instead of alleging an injury "caused *directly* by [Purdue's] alleged fraud," Plaintiff alleges it was harmed "*indirectly* . . . as a result of [Purdue's] misleading of *others*" -- doctors and their patients. *Desiano*, 326 F.3d at 340, 349 n.9 (emphases added). Because such a claim necessarily "rests on the independent choices of doctors" *and* patients, it is "too speculative to establish a causal link between the alleged injury and the alleged misconduct." *In re Guidant Corp.*, 484 F. Supp. 2d 973, 984 (D. Minn. 2007); *see also Allen*,

468 U.S. at 757 (injury resulting "'from the independent action of some third party not before the court,'" cannot satisfy Article III because the chain of causation "is attenuated at best") (citation omitted).

***Second***, Plaintiff's RICO claim fails for the additional reason that it lacks two essential elements of RICO's heightened requirement for proximate cause: Plaintiff does not allege that it was *directly* injured by defendants' conduct, and it does not allege that it *relied* on any specific misleading statement. Furthermore, Plaintiff fails to adequately allege a RICO "enterprise." The Abbott Defendants ("Abbott") and the Doe Defendants cannot be considered part of the alleged "enterprise" because Plaintiff makes only conclusory allegations regarding them. That leaves only Purdue and its own employees and agents. An enterprise cannot consist only of a company doing business with its employees and agents. Accordingly, Plaintiff's putative civil RICO claims "'are nothing more than sheep masquerading in wolves' clothing.'" *Kirk v. Heppt*, 423 F. Supp. 2d 147, 149-50 (S.D.N.Y. 2006) (quoting *W. 79th St. Corp. v. Congregation Kahl Minchas Chinuch*, No. 03 Civ. 8606 (RWS), 2004 WL 2187069, at *5 (S.D.N.Y. Sept. 30, 2004)).

***Third***, Plaintiff has not pleaded the required elements of a cause of action under the New Mexico Unfair Practices Act ("UPA"). To start with, Plaintiff, a third-party payor that simply reimburses its members for *their* purchases of OxyContin is not a "buyer" of OxyContin and therefore is not among the class of persons protected by the UPA. Nor has Plaintiff pleaded that it suffered an ascertainable loss as a result of Purdue's alleged conduct. On the contrary, the very "fraud on the market" theory it propounds here was recently rejected by the New Jersey Supreme Court in a case indistinguishable from this one (albeit arising under New Jersey law). *See Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co.*, 929 A.2d 1076, 1088 (N.J. 2007). Moreover, application of the UPA to the alleged misconduct here would be

inconsistent with New Mexico's adoption of the "learned intermediary doctrine," under which a prescription drug manufacturer's duty to warn runs only to physicians, not to remote third-party payors. Additionally, this claim is preempted by the Food, Drug, & Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et. seq.* As the Third Circuit recently held, "generalized state consumer fraud laws" like that invoked by Plaintiff are preempted by the FDCA and FDA regulations because they "pose an undue obstacle to both Congress's and the FDA's objectives in protecting the nation's prescription drug users." *Pa. Employees Benefit Trust Fund v. Zeneca, Inc.*, 499 F.3d 239, 251 (3d Cir. 2007).

***Fourth***, all Plaintiff's claims fail for the additional reason that they are barred by the applicable statutes of limitation.

***Fifth***, Plaintiff's unjust enrichment claim fails because there is no direct relationship between the reimbursements allegedly paid by Plaintiff and any benefit received by Purdue.

## PLEADING STANDARDS

"The standard for addressing a Rule 12(c) motion for judgment on the pleadings is the same as that for a Rule 12(b)(6) motion to dismiss for failure to state a claim." *Cleveland v. Caplaw Enterprises*, 448 F.3d 518, 521 (2d Cir. 2006). Under this standard, "a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1964-65 (2007). Plaintiff therefore must "amplify a claim with some factual allegations in those contexts where such amplification is needed to render the claim *plausible*." *Iqbal v. Hasty*, 490 F.3d 143, 157-58 (2d Cir. 2007) (emphasis in original). Stated differently, plaintiff "must plead 'enough facts to state a claim to relief that is plausible on its face.'" *Vladimir v.*

*Cowperthwait*, No. 06 Civ. 5863(JGK), 2007 WL 1964157, at *1 (S.D.N.Y. July 3, 2007) (Koeltl, J.) (quoting *Bell Atlantic*, 127 S. Ct. at 1974).

Even under the notice pleading standard of FRCP 8(a), "'[c]onclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to [defeat] a motion to dismiss.'" *Achtman v. Kirby, McInerney & Squire, LLP*, 464 F.3d 328, 337 (2d Cir. 2006). In addition, Plaintiff must satisfy FRCP 9(b) to the extent that its claims are based on allegations of fraud. The Second Circuit has held that "to comply with Rule 9(b), 'the complaint must: (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.'" *Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 290 (2d Cir. 2006).

That "all" of Plaintiff's allegations of fraud are based "upon information and belief," (Compl. p. 2), does not give it "license to base claims of fraud on speculation and conclusory allegations," *Wexner v. First Manhattan Co.*, 902 F.2d 169, 172 (2d Cir. 1990). To the contrary, "[w]here pleading is permitted on information and belief, a complaint must adduce *specific facts* supporting a strong inference of fraud or it will not satisfy *even a relaxed pleading standard*." *Id.* (emphases added); *Vento & Co. of N.Y. v. Metromedia Fiber Network, Inc.*, No. 97 CIV. 7751 (JGK), 1999 WL 147732, at *7 (S.D.N.Y. Mar. 19, 1999) (Koeltl, J.) (same).

## ARGUMENT

### I. PLAINTIFF LACKS STANDING

To satisfy the requirements for Article III standing for each of its claims, Plaintiff must show (1) a concrete and particularized injury-in-fact that is not conjectural or hypothetical, (2) a causal connection between the injury and the conduct complained of, and (3) a likelihood, not just mere speculation, that a favorable decision will redress the injury. *See LaFleur v. Whitman*,

300 F.3d 256, 269 (2d Cir. 2002). Article III mandates that "inferences favorable to the party asserting jurisdiction should not be drawn" and the requirements for Article III standing "must affirmatively appear in the record." *See Atl. Mut. Ins. Co. v. Balfour Maclaine Int'l Ltd.*, 968 F.2d 196, 198 (2d. Cir. 1992). If a plaintiff lacks standing, the court must dismiss the case. *See Cent. States Southeast & Southwest Areas Health & Welfare Fund v. Merck-Medco Managed Care, L.L.C.*, 433 F.3d 181, 198 (2d. Cir. 2005).

**A. Plaintiff Cannot Establish the Requisite Injury-In-Fact.**

Plaintiff cannot establish an injury-in-fact here because it concedes that it ***continues to this day to reimburse its members for their OxyContin prescriptions.*** (Compl. ¶¶ 3.) Purdue is unaware of any court in the nation that has ruled that a plaintiff has alleged an injury that is cognizable under Article III where, as here, its claims are based on a "fraud on the market" theory and it "*continue[s] to purchase [the drug] even though they are purportedly now aware of the 'truth' regarding its alleged lack of [the touted] benefits.*" *Prohias*, 485 F. Supp. 2d at 1332, 1335 (dismissing individual plaintiffs' claims as "too speculative to constitute an injury-in-fact under Article III") (emphasis added); *see also Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1332 n.3 (S.D. Fla. 2007) (applying same reasoning to dismiss TPP's attempt to "seek recovery of any alleged overpayments based on a 'price inflation' theory"); *Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171 (D.D.C. 2003) (where, as here, plaintiffs alleged only that they paid "a higher price for OxyContin because of defendants' promotional tactics," plaintiffs had no standing because they "fail[ed] to allege any particularized and specific injury-in-fact suffered by [them]").

There is no allegation here that "if not for [Purdue's alleged] deceptive advertising campaign, [Plaintiff] would have excluded [OxyContin] from approved formulary schedules, set

a lower value in the formulary, or set a higher co-pay obligation." *Prohias*, 490 F. Supp. 2d at 1232. Nor does Plaintiff allege that it "would not have bought [OxyContin], rather than available cheaper alternatives, had [it] not been misled by [the alleged] misrepresentations." *Desiano*, 326 F.3d at 349. To the contrary, no alternative medication is mentioned in the Complaint, and ***Plaintiff continues to make payments for OxyContin even though the medication's price remains "artificially high."*** (Compl. ¶ 75.[2]) Given the facts alleged here, Plaintiff cannot be deemed to have alleged a cognizable injury-in-fact under Article III. *See, e.g., In re Guidant*, 484 F. Supp. 2d at 983 (distinguishing *Desiano* because, as here, the TPP plaintiffs could not establish the kind of direct relationship between themselves and the defendant -- *e.g.*, actual reliance on the alleged misconduct in purchasing the defendants' drug instead of cheaper alternatives -- from which a cognizable injury could arise).

### B. Plaintiff Cannot Establish the Requisite Causal Nexus Between Its Alleged Injury and Purdue's Alleged Misconduct.

Plaintiff also lacks standing because it cannot establish the requisite "causal connection between the injury and the conduct complained of," *i.e.*, that the injury is "fairly traceable to the challenged action of the defendant and not the result of the independent action of some third party not before the court." *In re Guidant*, 484 F. Supp. 2d at 984. *None* of the wrongful conduct specified in the Complaint was directed towards Plaintiff. To the contrary, the Complaint alleges only conduct directed toward healthcare providers and consumers, as the following examples show:

- Purdue "used two key promotional messages for primary physicians and other high prescribers." (Compl. ¶ 30.)

[2] Nothing in the Complaint suggests that the purported "artificially high" price has decreased since the alleged misrepresentations came to light.

- Purdue used "marketing tactics aimed directly at consumers." (*Id.* ¶ 36.)
- Purdue sales representatives "misbranded" OxyContin in statements made to "health care providers." (*Id.* ¶¶ 53, 58-59.)

Indeed, Plaintiff *concedes* that the only conduct alleged here was "***aimed at physicians, hospitals, pharmacists, and patients***." (Compl. ¶ 29 (emphasis added).)

Because Plaintiff has thus conceded that it was not "directly harmed by [any] deception practiced on *[it]*," the Complaint cannot be construed as alleging that Plaintiff was a "*direct victim*[ ] of [Purdue's] fraudulent marketing." *Desiano*, 326 F.3d at 349 n.9, 351. *See, e.g.*, *In re Rezulin Prods. Liab. Litig.*, --- F. Supp. 2d ---, 2007 WL 4165703, at *3 (S.D.N.Y. Nov. 26, 2007) (rejecting third-party payors' contention that "they are entitled to recover because defendants misled patients and the medical community concerning the safety and efficacy of Rezulin in consequence of which, they claim, [they were] called upon to reimburse for prescriptions that otherwise would not have been written at prices that otherwise could not have been charged").[3]

Unable to identify conduct directed toward it, Plaintiff is left asserting that that Purdue "developed this marketing and advertising strategy *with the intent* that . . . third party payors would place OxyContin on their formularies." (Compl. ¶ 29 (emphasis added).) But Plaintiff

[3] In sharp contrast, *Desiano* involved "claims of damages that were caused directly by [the] alleged fraud" because the defendant "misrepresented its product *to Plaintiffs*." 326 F.3d at 340, 350; *see also In re Rezulin*, 2007 WL 4165703, at *3 ("*Desiano* made clear that it upheld the complaint because the [third-party payor] plaintiffs alleged that they themselves had been misled as purchasers of the drug.") (distinguishing *Desiano* because the *Rezulin* TPP plaintiff alleged only that it was the victim of a fraud on the market "and not because [it] was itself deceived."); *In re Guidant*, 484 F. Supp. 2d at 983 (distinguishing *Desiano* on ground that "there are no allegations that the named TPP Plaintiffs agreed to pay a certain price for the devices based on [the manufacturer's] statements or to grant [the manufacturer] some sort of preferred or approved provider status" based on such statements).

fails to allege that Purdue took any *action* to further its "intent." Because "intent" alone cannot have injured Plaintiff, its assertions about "intent" are irrelevant.[4]

Because Plaintiff thus alleges only that Purdue made misrepresentations to healthcare providers and patients, its theory of causation "rests on the *independent choices* of the doctors who recommend[ed] [OxyContin] to their patients and on the patients who decide[d] to receive the [medication], in lieu of other treatment options, if any." *In re Guidant Corp.*, 484 F. Supp. 2d at 984 (emphasis added). Thus, "the causation link would depend on concluding that had [Purdue] acted lawfully, the doctor would not have prescribed the drug and the patient would not have taken it," and such a conclusion is "too speculative to establish a causal link between the alleged injury and the alleged misconduct." *Id.*; *see also In re Rezulin*, 2007 WL 4165703, at *3 (no causal nexus where "plaintiffs allege[d] that they were injured because patients and the medical community were misled"). Plaintiff's alleged injury is not "fairly . . . traceable to the challenged action[s]" by Purdue because it resulted from "the independent action of some third part[ies] not before the court." *Cent. States Southeast*, 433 F.3d at 198. Thus, the causal nexus required under Article III is absent here.

Because Plaintiff lacks standing, the Complaint should be dismissed in its entirety.

## II. PLAINTIFF'S RICO CLAIMS

Courts in this Circuit "'look[ ] with particular scrutiny at civil RICO claims'" even without regard to Rule 9(b). *City of N.Y. v. Cyco.Net, Inc.*, 383 F. Supp. 2d 526, 546 (S.D.N.Y.

[4] The Court should disregard the conclusory allegation that Plaintiff "relied upon Defendants' misrepresentations and omissions in paying for OxyContin" (Compl. ¶ 165; *see also id.* ¶ 93) because Plaintiff does not allege any facts to support it, whereas the facts that are alleged – *i.e.*, that Purdue's marketing targeted healthcare providers and consumers – contradict it. *See, e.g.*, *Twombley*, 127 S.Ct. at 1964-65 (a plaintiff must provide more than "labels and conclusions"); *In re Guidant*, 484 F.Supp.2d at 983 (rejecting TPP plaintiffs' assertion that they "suffered direct injuries" where complaint provided no support for that assertion).

2005). Such scrutiny is needed for a number of reasons. To begin with, "'the civil provisions of [RICO] are the most misused statutes in the federal corpus of law.'" *W. 79th St. Corp.*, 2004 WL 2187069, at *5; *Pacific Elec. Wire & Cable Co. v. Set Top Int'l, Inc.*, No. 03 Civ. 9623 (JFK), 2005 WL 578916, at *13 (S.D.N.Y. Mar. 11, 2005) (same); *Goldfine v. Sichenzia*, 118 F. Supp. 2d 392, 394 (S.D.N.Y. 2000) (same). At the same time, the mere pendency of a baseless RICO claim can "unfairly sully [an individual] defendant's reputation." *Gerstenfeld v. Nitsberg*, 190 F.R.D. 127, 133 (S.D.N.Y. 1999). Indeed, "[t]he consequences to *anyone* of being accused of *racketeering* are dire. As this court has long recognized, 'the *mere assertion* of a RICO claim . . . has an *almost inevitable stigmatizing effect on those named as defendants*.'" *Carousel Foods of Am., Inc. v. Abrams & Co., Inc.*, 423 F. Supp. 2d 119, 123 (S.D.N.Y. 2006) (quoting *Katzman v. Victoria's Secret Catalogue*, 167 F.R.D. 649, 655 (S.D.N.Y. 1996), *aff'd*, 113 F.3d 1229 (2d Cir. 1997)) (emphases added). Further, the "possibility of treble damages" makes a RICO claim "an 'unusually potent weapon'" – "the litigation equivalent of a thermonuclear device" – that, if not closely examined at the pleadings stage, can create intense pressure to settle regardless of its merit. *Cedar Swamp Holdings, Inc. v. Zaman*, 487 F. Supp. 2d 444, 449 (S.D.N.Y. May 17, 2007) (quoting *Katzman*, 167 F.R.D. at 655). For all of these reasons, it is well-established in this Circuit that "'courts should strive to flush out frivolous RICO allegations at an early stage in the litigation.'" *At The Airport v. ISATA, LLC*, 438 F. Supp. 2d 55, 61 (E.D.N.Y. 2006).

These principles apply with special force here. Even if Plaintiff had standing to bring its RICO claims – and it does not, as shown above – the claims would fail because it has not adequately alleged that Purdue's alleged misconduct proximately caused any harm to it or that the various defendants named in the Complaint constituted a RICO "enterprise."

### A. Proximate Causation Pursuant to RICO Requires a Direct Injury and Reliance.

"RICO provides a private right of action for '[a]ny person injured in his business or property *by reason of* a violation of section 1962 of this chapter.'" *Lerner*, 459 F.3d at 283 (quoting 18 U.S.C. § 1964(c)). "'RICO's use of the clause 'by reason of'" requires that plaintiff must "'allege that the asserted RICO violation was the legal, or proximate, cause of [its] injury, as well as a logical, or 'but for,' cause.'" *Id.* at 283-84 (quoting *Commercial Cleaning Servs., L.L.C. v. Colin Serv. Svs., Inc.*, 271 F.3d 374, 380 (2d Cir. 2001)). "[T]he proximate cause requirements of RICO [are] more stringent than those" of most state-law causes of action. *Desiano*, 326 F.3d at 348.[5] To satisfy those requirements here, Plaintiff must allege two elements "independent of and in addition to other traditional elements of proximate cause." *Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 235-36 (2d Cir. 1999).

*First*, as the Supreme Court recently reaffirmed, RICO demands "'some *direct relation* between the injury asserted and the injurious conduct alleged.'" *Anza v. Ideal Steel Supply Corp.*, 126 S. Ct. 1991, 1996 (2006) (emphasis added) (quoting *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258, 268 (1992)). The Supreme Court explained that when the alleged injury was "caused by some remote action," it is "'difficult . . . [to] ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent factors.'" *Id.* at 1997 (quoting *Holmes*, 503 U.S. at 269). Emphasizing that RICO's heightened proximate causation requirement "prevent[s] these types of intricate, uncertain inquiries from overrunning

[5] No RICO claim was at issue in *Desiano*, which involved claims under "New Jersey common law," and thus the Second Circuit did not apply RICO's "more stringent" proximate causation standard in that case. *Desiano*, 326 F.3d at 348.

RICO litigation," the Supreme Court rejected an attempt "to broaden the universe of actionable harms to permit RICO suits by parties who have been injured only indirectly." *Id.* at 1998.

*Second*, "[i]t is well established in this Circuit that where mail [or wire] fraud is the predicate act for a civil RICO claim, the proximate cause element . . . requires the plaintiff to show reasonable reliance." *Bank of China, N.Y. Branch v. NBM, LLC*, 359 F.3d 171, 176 (2d Cir. 2004). Here, because mail and wire fraud are the alleged predicate acts for Plaintiff's RICO claim (Compl. ¶¶ 92-95), Plaintiff "must establish 'reasonable reliance' on the defendants' purported misrepresentations or omissions," *Bank of China*, 359 F.3d at 178.

**1. Plaintiff Fails to Allege a Direct Injury.**

"When a court evaluates a RICO claim for proximate causation, the central question it must ask is whether the alleged violation led *directly* to the plaintiff's injuries." *Anza*, 126 S. Ct. at 1998 (emphasis added). Here, however, the alleged fraudulent statements were allegedly made to non-parties (healthcare providers and patients) and allegedly injured Plaintiff only indirectly by allegedly increasing the "market share of OxyContin," thus allowing Purdue "to charge more for OxyContin than they otherwise would have been able to charge," which, in turn, led to Plaintiff allegedly paying "artificially high costs of filling OxyContin prescriptions." (Compl. ¶¶ 1, 38, 75.) This attenuated chain of causation falls far short of establishing the requisite "'direct relation between the injury asserted and the injurious conduct alleged.'" *Anza*, 126 S. Ct. at 1996.[6]

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[6] *See, e.g., Int'l Bhd. of Teamsters, Local 734 Health & Welfare Trust Fund v. Philip Morris Inc.*, 196 F.3d 818, 825-26 (7th Cir. 1999) (health benefit funds failed to allege a direct injury, and thus could not establish proximate causation under RICO, where "[t]he 'racketeering acts' of which [they] complain[ed] all concern[ed] alleged misstatements about the relation between smoking and health" that "were not made to the Funds" and "affected the Funds . . . (if at all) only because they may have influenced smokers").

The indirect nature of the harm alleged by Plaintiff is highlighted by the fact that it could not have occurred without intervening acts by independent third parties (*i.e.*, prescribers and users of OxyContin). The Second Circuit has recognized in the RICO context "when factors other than the defendant's fraud are an intervening direct cause of a plaintiff's injury, that same injury cannot be said to have occurred by reason of the defendant's actions." *First Nationwide Bank v. Gelt Funding Corp.*, 27 F.3d 763, 769 (2d Cir. 1994). Thus, "'it is usually easier for intervenors to break the chain of causation in RICO than it is at common law.'" *Lerner*, 459 F.3d at 285 n.5 (quoting *Moore v. PaineWebber, Inc.*, 189 F.3d 165, 179 (2d Cir. 1999) (Calabresi, J., concurring)). Plaintiff cannot establish proximate causation based on allegedly misleading statements that were made only to such "intervenors," not to Plaintiff.[7]

**2. Plaintiff Fails to Allege Reliance.**

Proximate causation is also lacking because Plaintiff fails to allege "that it reasonably relied on defendants' purported misrepresentations." *Bank of China*, 359 F.3d at 178. The *only* specific allegedly misleading statements cited by Plaintiff were allegedly made *to healthcare providers and patients*. (*E.g.*, Compl. ¶¶ 29-36, 53.) Because Plaintiff does *not* allege that defendants made any specific misleading statement to *it* – let alone that it relied on any such statement when it made payments for OxyContin – Plaintiff has failed to allege the essential element of reliance. *See Burrell v. State Farm & Cas. Co.*, 226 F. Supp. 2d 427, 439 (S.D.N.Y.

[7] Without addressing *Anza*, the court in *In re Zyprexa Products Liability Litigation*, 493 F. Supp. 2d 571 (E.D.N.Y. 2007) (Weinstein, J.), wrongly concluded that where TPPs claimed that they "paid for the drug Zyprexa when it was prescribed by physicians" for the TPPs' members based on false representations to the physicians that it was "safer and more efficacious than other available drugs," the TPPs alleged "a direct injury to themselves that is not dependent on any physician's decision." *Id.* at 574, 577-78. That the drug was "prescribed by physicians" (based on false representations to them), however, makes clear that the alleged injury was dependent on their separate and independent prescribing decisions. Even under the Second Circuit precedent that existed before *Anza*, such intervening decisions preclude a plaintiff from establishing proximate causation. *See First Nationwide Bank*, 27 F.3d at 769.

2002) (Koeltl, J.) ("none of the statements that the plaintiffs identify with particularity are instances of fraud because the plaintiffs have not alleged that *they relied upon any* of these allegedly false statements") (emphasis added).[8]

**B. Plaintiff Fails to Adequately Allege a RICO Enterprise.**

Plaintiff alleges violations of 18 U.S.C. § 1962(c) and (d). Section 1962(c) provides: "It shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." Section 1962(d) makes it "unlawful for any person to conspire to violate" § 1962(c). To establish a violation of § 1962(c), a plaintiff must show "'(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity'" (5) that had at least "a minimal effect on interstate commerce." *DeFalco v. Bernas*, 244 F.3d 286, 306, 309 (2d Cir. 2001). Here it is necessary only to discuss the "enterprise" element.

While RICO provides that an "enterprise" can be "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity," 18 U.S.C. § 1961(4), "[t]he Supreme Court has explained that a RICO enterprise is 'a group of persons associated together for a common purpose of engaging in a course of conduct,' the existence of which is proven 'by evidence of an ongoing organization,

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[8] The analysis is not affected by Plaintiff's conclusory allegations that "in paying for OxyContin" it "relied upon" unspecified "misrepresentations" by and "communications with" defendants (Compl. ¶¶ 93(d), 165) because Plaintiff identifies no particular such communication to support its fraud-based RICO claims. *See, e.g.*, *ATSI Communications, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007) (under Fed. R. Civ. P. 9(b), "[a]llegations that are conclusory or unsupported by factual assertions are insufficient"); *Bank of Am. Corp. v. Lemgruber*, 385 F. Supp. 2d 200, 230 (S.D.N.Y. 2005) ("As 'an essential element of a cause of action for fraud . . . [justifiable] reliance must be pleaded with particularity' pursuant to [Rule] 9(b).") (quoting *Lutin v. New Jersey Steel Corp.*, No. 93 Civ. 6612, 1996 WL 636037, at * 7 (S.D.N.Y. Nov. 1, 1996)) (first alteration and omission in original).

formal or informal, and by evidence that the various associates function as a continuing unit.'" *First Capital Asset Mgmt., Inc. v. Satinwood, Inc.*, 385 F.3d 159, 173 (2d Cir. 2004) (quoting *United States v. Turkette*, 452 U.S. 576, 583 (1981)). The individuals "'must share a common purpose to engage in a particular fraudulent course of conduct and work together to achieve such purposes.'" *Id.* at 174. Importantly, "any legal entity may qualify as a RICO enterprise," but only if, among other things, the entity is "distinct from the person conducting the affairs of the enterprise." *Id.* at 173-74.

The RICO "enterprise" alleged by Plaintiff is a purported "Off-Label Promotion Enterprise" consisting of all the defendants ("the Purdue Defendants, the Abbott Defendants, including their employees and agents, the Individual Defendants and the Does"). (Compl. ¶¶ 87-88.) Plaintiff alleges that the supposed members of the purported enterprise "acted to promote OxyContin for off-label uses in contravention of FDA regulations" and shared the "common purpose" of engaging in such off-label promotion. (*Id.* ¶¶ 88-89.) But, whereas Plaintiff devotes many paragraphs to Purdue's alleged bad acts, it makes only vague and conclusory allegations of wrongdoing by Abbott and the Doe Defendants. The purported enterprise thus consists only of Purdue and its employees and agents, and the Second Circuit has repeatedly held that a RICO enterprise cannot consist only of a corporation and its own employees and agents carrying on its regular business activities, as is alleged here.

**1. Plaintiff's Conclusory Naming of Abbott and the Doe Defendants Cannot Render Them Members of the Purported RICO Enterprise.**

The "enterprise" element is adequately alleged only if the complaint "explain[s] each participant's role in the alleged course of fraudulent or illegal conduct"; the "'conclusory naming of a string of entities does not adequately allege an enterprise.'" *Satinwood*, 385 F.3d at 175

(quoting *Moy v. Terranova*, No. 87 CV 1578 (SJ), 1999 WL 118773, at *5 (E.D.N.Y. Mar. 2, 1999)). *None* of Plaintiff's allegations regarding Abbott or the Doe Defendants, however, involves a specific improper act of any kind – let alone a specific *fraudulent* act related to OxyContin. (*Id.* ¶¶ 11-13, 23, 67-71, 88.) Indeed, Plaintiff names Abbott and the Doe Defendants as participants in the "Off-Label Promotion Enterprise" without alleging *any* fact that, if true, would make it plausible that they shared a "common purpose" to "promote OxyContin for off-label uses in contravention of FDA regulations." (Compl. ¶¶ 88-89.) On the contrary, Plaintiff's *only* allegations of *improper* acts by Abbott and the Doe Defendants are *general allegations against all the defendants* that provide no indication of what role (if any) Abbott and the Doe Defendants played in the purported "Off-Label Promotion Enterprise." (*E.g.*, *id.* ¶¶ 88 (all defendants "acted to promote OxyContin for off-label uses in contravention of FDA regulations").) Similarly, on the issue of whether the members of the supposed enterprise shared a common purpose, Plaintiff makes no allegation specific to Abbott or the Doe Defendants. Instead, Plaintiff alleges generally that "Defendants" had the common purpose of "marketing OxyContin for off-label uses." (*Id.* ¶ 89.) Accordingly, Plaintiff's "fail[ure] to explain [either Abbott or any Doe Defendant's] role in the alleged course of fraudulent or illegal conduct" – let alone to show that they "share[d] a common purpose to engage in" that alleged course of conduct – renders the "conclusory naming" of Abbott and the Doe Defendants irrelevant to whether the complaint adequately alleges an "enterprise." *Satinwood*, 385 F.3d at 175.[9]

[9] In *JSC Foreign Economic Association Technostroyexport v. Weiss*, No. 06 Civ. 6095 (JGK), 2007 WL 1159637 (S.D.N.Y. Apr. 18, 2007), this Court concluded that the statement in *Satinwood* that a RICO plaintiff "must allege a 'course of fraudulent or illegal conduct separate and distinct from the alleged predicate racketeering acts themselves'" conflicted with a prior Second Circuit opinion. *JSC Foreign*, 2007 WL 1159637, at *9 (quoting *Satinwood*, 385 F.3d at

That Abbott entered into a co-promotion agreement with Purdue does not make it "'plausible on its face'" that Abbott made unidentified misleading statements. *Vladimir*, 2007 WL 1964157, at *1 (quoting *Bell Atlantic*, 127 S. Ct. at 1974). To the contrary, Plaintiff does not allege that the co-promotion agreement required Abbott to make any specific representations about OxyContin, much less that Abbott was to provide misleading information to prescribers. Therefore, the Court should disregard Plaintiff's conclusory assertion, "upon information and belief, that, as Purdue's chosen and retained co-promoter of OxyContin, the Abbott Defendants utilized the same deceptive and aggressive marketing tactics as those utilized by Purdue." (Compl. ¶ 67.)

**2. Purdue and Its Employees and Agents Cannot Be a RICO Enterprise.**

Once the conclusory allegations regarding Abbott and the Doe Defendants are disregarded (as they must be), the purported "Off-Label Promotion Enterprise" is reduced to Purdue and its employees and agents. The Second Circuit has repeatedly held, however, that "where employees of a corporation associate together to commit a pattern of predicate acts in the course of their employment and on behalf of the corporation, the employees in association with the corporation do not form an enterprise distinct from the corporation." *Riverwoods Chappaqua Corp. v. Marine Midland Bank, N.A.*, 30 F.3d 339, 344 (2d Cir. 1994). Thus, a plaintiff "cannot circumvent the distinctness requirement 'by alleging a RICO enterprise that consists merely of a corporate defendant associated with its own employees or agents carrying on the regular affairs

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174). Regardless of any such conflict, however, the statement in *Satinwood* that was involved in *JSC Foreign* is not relevant here. And even if construed as *dicta*, *see JSC Foreign*, 2007 WL 1159637, at *9, the portions of *Satinwood* that address the distinct issue relevant here – whether the conclusory naming of purported members can establish a RICO enterprise – correctly state the law in this Circuit.

of the defendant.'" *Anatian v. Coutts Bank (Switzerland) Ltd.*, 193 F.3d 85, 89 (2d Cir. 1999) (quoting *Riverwoods*, 30 F.3d at 344).[10]

Here, because Plaintiff's allegations against Purdue and its employees and agents involve "carrying on the regular affairs of [Purdue]," these individuals' "association with [Purdue] do[es] not form an enterprise distinct from [Purdue]." *Riverwoods*, 30 F.3d at 344. Plaintiff thus fails adequately to allege a RICO enterprise. *See Burrell v. State Farm & Cas. Co.*, 226 F. Supp. 2d 427, 443 (S.D.N.Y. 2002) (Koeltl, J.) ("As [the RICO defendant] correctly argues, "'[a] corporate entity may not be simultaneously the enterprise and the person who conducts the affairs of the enterprise through a pattern of racketeering activity.'") (quoting *Anatian*, 193 F.3d at 88-89) (second alteration in original); *R.C.M. Executive Gallery Corp. v. Rols Capital Co.*, No. 93 Civ. 8571 (JGK), 1997 WL 27059, at *7 (S.D.N.Y. Jan. 23, 1997) (Koeltl, J.) ("A corporate entity cannot be both the RICO person and the RICO enterprise under § 1962(c).").

That Purdue Pharma L.P. is a partnership rather than a corporation does not affect the analysis under *Riverwoods*. As in *R.C.M. Executive Gallery Corp. v. Rols Capital Co.*, 901 F. Supp. 630 (S.D.N.Y. 1995) (Koeltl, J.), here Plaintiff fails to allege a RICO enterprise because it "offer[s] no evidence that the partnership and the individual defendants had any association aside from the ordinary business of the partnership." *Id.* at 639-41 (applying *Riverwoods*).

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[10] The Supreme Court has indicated approval of *Riverwoods*, explaining that "the person and the victim, or the person and the tool, [must be] distinct entities, not the same" for a corporation to be a participant in a RICO enterprise. *Cedric Kushner Promotions, Ltd. v. King*, 533 U.S. 158, 161, 164 (2001) (citing *Riverwoods*, 30 F.3d at 344). Since *Kushner*, courts in this Circuit have applied *Riverwoods* to situations like the one here. *See City of N.Y. v. Nexicon, Inc.*, No. 03-CV-383(DAB), 2006 WL 647716, at *9 (S.D.N.Y. Mar. 15, 2006) ("an enterprise cannot merely be comprised of employees associating with their corporate employer"); *Manhattan Telecomm. Corp. v. DialAmerica, Inc.*, 156 F. Supp. 2d 376, 382 n.4 (S.D.N.Y. 2001) ("in its original complaint, plaintiff alleged that the RICO enterprise consisted only of DialAmerica and the Individual Defendants, thereby running afoul of the distinctness requirement.")

* * * * *

Finally, because Plaintiff fails adequately to allege a RICO enterprise, its "1962(d) conspiracy claim cannot survive." *Hoatson v. N.Y. Archdiocese*, No. 05 Civ. 10467(PAC), 2007 WL 431098, at *6 (S.D.N.Y. Feb. 8, 2007); *see also Citadel Mgmt., Inc. v. Telesis Trust, Inc.*, 123 F. Supp. 2d 133, 156 (S.D.N.Y. 2000) ("a RICO conspiracy claim cannot stand where, as here, the elements of the substantive RICO provisions are not met").

## III. PLAINTIFF FAILS TO STATE A CLAIM UNDER THE UPA.

The governing consumer protection statute here is New Mexico's UPA. *See In re Rezulin Prods. Liab. Litig.*, 392 F. Supp. 2d 597, 606-07, 611-12 (S.D.N.Y. 2005) (applying consumer fraud statute of state where plaintiff allegedly suffered harm).[11]

To recover for a violation of the UPA, a plaintiff must be a "buyer." *Santa Fe Custom Shutters & Doors, Inc. v. Home Depot U.S.A., Inc.*, 113 P.3d 347, 352-53 (N.M. App. 2005), *cert denied*, 113 P.3d 345 (N.M. 2005). Further, a plaintiff must show that: (1) the defendant made an oral or written statement that was false or misleading, (2) the false or misleading representation must have been knowingly made in connection with a sale or service, (3) the conduct complained of occurred in the regular course of the defendant's business, and (4) the representation may, tends to or does, deceive or mislead any person. *Brooks v. Norwest Corp.*, 103 P.3d 39, 51 (N.M. App. 2004) (quoting *Ashlock v. Sunwest Bank of Roswell*, 753 P.2d 346, 347 (N.M. 1988), *overruled on other grounds by Gonzales v. Surgidev Corp.*, 899 P.2d 576, 583

[11] In the Complaint, Plaintiff cites the consumer fraud statutes of some 47 states, including New Mexico. (Compl. ¶¶ 115-162.) Presumably this is because Plaintiff purports to represent a putative "nationwide" class and not because it purports to state a claim under each statute. Because this motion is directed to the claims asserted by the Plaintiff individually (and not to those claims that might be asserted by absent members of a class were it to be certified), such other states' statutes are not relevant to the 12(c) analysis.

(N.M. 1988)). In addition, a plaintiff must demonstrate that it suffered a loss of money or property as a result of the UPA violation. *See* N.M. Stat. Ann. § 57-12-10(B). As set forth below, Plaintiff's allegations fall well short of pleading a violation of the UPA.

**A. Plaintiff Is Not A Buyer and Thus Lacks Standing Under the UPA.**

As New Mexico courts have unequivocally held: "Consistent with its purpose as *consumer* protection legislation . . . the UPA gives standing only to buyers of goods and services." *Santa Fe*, 113 P.3d at 353 (emphasis added). The UPA, therefore, only applies to "a plaintiff who seeks or acquires goods or services and a defendant who provides goods or services." *Id.* at 352.

Plaintiff in this case is not a buyer of OxyContin. As a third-party payor, Plaintiff is in the business of providing prescription drug benefits to its participants. As such, Plaintiff's business consists of fulfilling its contractual obligation to *reimburse* its members for *their purchases* of prescription drugs. Indeed, as described in the Complaint, what Plaintiff does bears no resemblance to what a buyer does when he/she purchases a consumer product. Plaintiff does not allege that it has any role in determining whether the drug in question is medically appropriate in the case of individual prescribing decisions. Nor does Plaintiff allege that it takes "title" or possession of any of the drugs its members purchase. Plaintiff does what it is required to do: reimburse its members for the medicines their doctors independently prescribe and they (the members) chose to purchase and take. In short, Plaintiff is simply not a member of the class of persons -- "buyers" -- with standing to sue under the UPA. *See, e.g., Nanodetex Corp. v.*

*Sandia Corp.*, No. 05-1041, 2007 WL 4356154, at *6 (D.N.M., July 26, 2007) (citing *Sante Fe*, 113 P.3d at 352).[12]

**B. There is No Causal Link Between Plaintiff's "Loss" and Purdue's Conduct.**

The UPA requires "proof of a causal link between conduct and loss." *Smoot v. Physicians Life Ins. Co.*, 87 P.3d 545, 550 (N.M. App. 2003); *see also Mulford v. Altria Group, Inc.*, 242 F.R.D. at 615, 622 (D.N.M. 2007) (noting that a plaintiff must prove that it "suffered a loss of money or property as a result of the deceptive conduct"). As discussed in Section I(B) above, Plaintiff has not alleged that Purdue made any misrepresentation to it or how any alleged misrepresentation caused it to make the decision to pay for OxyContin. Instead, Plaintiff relies on a "fraud-on-the-market" theory of causation. (*See supra* Section I; Compl. ¶¶ 1, 38, 72, 75, 114, 170.)

As the New Jersey Supreme Court recently made clear in a case virtually indistinguishable from this one, "fraud on the market" is not a viable theory under state consumer fraud statutes like the UPA. *See Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co.*, 929 A.2d 1076, 1088 (N.J. 2007). In the *Merck* case -- which was, like this one, brought on behalf of a putative nationwide class of third-party payors -- the plaintiffs argued that they could establish an ascertainable loss by offering "expert proof" that the defendants' misconduct caused the plaintiffs to pay an artificially inflated price for the defendant's drug. In rejecting this argument, the New Jersey Supreme Court explained that this

[12] In *dicta*, the *Desiano* court noted that, in the federal antitrust context, there is authority that an insurer can be considered a buyer of prescription pharmaceuticals to the extent the insurer alleges that it has entered into reimbursement contracts with pharmacy companies. *See Desiano*, 326 F.3d at 350 (discussing antitrust cases). This is not, of course, a federal antitrust case. The question here is whether Plaintiff is a buyer under New Mexico law. In any event, unlike the TPPs in *Desiano*, Plaintiff does not even assert that it is a "buyer" or "purchaser" of OxyContin. *Compare id.* at 350-51 (accepting plaintiffs' assertion that they were purchasers of Rezulin).

theory "would indeed be the equivalent of fraud on the market, a theory we have not extended to CFA claims." *Id.*[13] The same result should apply here.

**C. The Learned Intermediary Doctrine Precludes Relief Under The UPA.**

Plaintiff's UPA claim fails for the additional reason that it falls outside the permissible scope of the UPA. The UPA is intended to regulate conducted directed at consumers. *See Jones v. General Motors Corp.*, 953 P.2d 1104, 1108-09 (N.M. App. 1998)(quoting *Ashlock*, 753 P.2d at 348). In the context of prescription medications, however, the "learned intermediary doctrine" directs drug manufacturers to provide warnings *to physicians, but not to patients (i.e. consumers). See, e.g., Serna v. Roche Labs.*, 684 P.2d 1187, 1189 (N.M. App. 1984).

Although New Mexico courts have not been asked to apply the learned intermediary doctrine specifically to UPA claims, other courts have determined that the doctrine necessarily precludes claims brought under consumer protection laws. *See, e.g., Heindel*, 381 F. Supp. 2d at 384 ("[T]o permit a cause of action under the [Pennsylvania consumer protection law] in this case would effectively make a drug manufacturer the absolute guarantor of anticipated results and effects of a prescription drug. Pennsylvania law, however, recognizes that some prescription

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[13] In rejecting a similar claim under Pennsylvania's consumer fraud statute, the district court in *Heindel v. Pfizer, Inc.*, 381 F.Supp.2d 364 (D.N.J. 2004), explained why "fraud on the market" makes no sense in the prescription drug context:

> [T]here is no prescription drug "market," at least as that term is understood in the securities context. There, a "perfect market" or "efficient market" is assumed, and adverse information is expected to be quickly absorbed by the market, thus causing the price of the stock or commodity at issue to fluctuate. But the only "market" for a prescription drug is the potential group of patients who will be prescribed it by their physician, and if the side effects of the drug make it overly risky to ingest, the doctor will either not prescribe it or the patients will decide not to take it. The suggestion that consumers might be inclined to take a drug with certain side affects if they could pay less for it, or that drugs with certain side effects should cost less, defies both reality and common sense.

*Id.* at 380.

drugs by their very nature can never be made safe."); *see also Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 552 (E.D. Pa. 2006) (finding that learned intermediary doctrine precluded claim under New York consumer statute); *In re Norplant Prods. Liab. Litig.*, 955 F. Supp. 700 (E.D. Tex. 1997) (holding that learned intermediary doctrine precluded claim under Texas consumer statute). As the *Colacicco* court concluded:

> [W]e agree that the learned intermediary doctrine also precludes Plaintiff's claim under the consumer protection statute. While the New York courts have yet to confront this specific issue, we believe our holding is entirely consistent with both the statute and the doctrine. This is because the consumer protection statute forbids deceptive acts of practices likely to mislead a reasonable *consumer*, specifically requiring proof that the defendant's acts are directed at consumers . . . while the LID dictates that all pharmaceutical information is directed at *physicians, not consumer-patients.* Applying other state consumer protection statutes, other courts have come to the same logical conclusion that the statute and the doctrine are inherently inconsistent with one another.

*Colacicco*, 432 F. Supp. 2d at 552 (alterations in original). The same analysis applies with even greater force here where Plaintiff is not even a consumer, but a remote third-party payor.

### D. Plaintiff's Consumer Protection Claim Is Preempted By The Food, Drug, & Cosmetic Act And FDA Regulations.

When state law conflicts with extensive federal law, implied conflict preemption renders state law "without effect." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). Such a conflict exists where either (1) the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" or (2) it is "impossible for a . . . party to comply with both state and federal law." *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 899 (2000). Recently, the U.S. Federal Court of Appeals for the Third Circuit applied these

principles to a case indistinguishable from this one. *See Pa. Employees Benefit Trust Fund v. Zeneca, Inc.*, 499 F.3d 239, 251 (3d Cir. 2007) (rehearing en banc denied).

As here, the third-party payor plaintiff in *Zeneca* brought suit "asserting that [drug maker] Zeneca engaged in deceptive conduct in the advertising of its new drug Nexium." *Id.* at 240. The district court summed up the plaintiffs' allegations this way:

> Plaintiffs allege that, once Prilosec could be sold as the generic drug omeprazole, defendants engaged in a massive advertising campaign to boost the sales of the more expensive prescription drug Nexium. In their advertisements, defendants "either implicitly or expressly represented" that Nexium was superior to Prilosec. In doing so, defendants "**suppressed and/or omitted**" information demonstrating that "Nexium . . . [is] not more effective at equivalent doses to the standard therapeutic dose of Prilosec." Plaintiffs assert that this **misleading advertising campaign** has resulted in "**billions of dollars of unnecessary drug expenditures by third party payors" and that "hundreds of thousands of patients have taken Nexium and continue to do so when they should not."**

*Pa. Employee Benefit Trust Fund v. Zeneca*, No. 05-075-SLR, 2005 WL 2993937, at *1 (D. Del., Nov. 8, 2005) (emphasis added).

The appellate court in *Zeneca* reviewed these allegations in light of the myriad rules and regulations governing prescription drug promotion and advertising and labeling. As the court explained, the FDA has promulgated extensive regulations governing labeling, *see* 21 C.F.R. pt. 201, and advertising, *see* 21 C.F.R. pt. 202, of prescription drugs. A drug manufacturer like Purdue cannot legally market a prescription drug like OxyContin in this country without FDA approval establishing that the drug is safe and effective for use in approved indications.[14] Prior

[14] *See, e.g.*, 21 U.S.C. § 355(b)(1)(A) (providing that a manufacturer is required to submit a New Drug Application ("NDA") which includes evidence "to show whether or not such drug is safe for use and whether such drug is effective in use"); 21 U.S.C. § 355(d) (providing that the FDA shall reject an NDA that is not safe and effective); 21 C.F.R. § 314.105(a) ("A new drug

to approval, the FDA determines what is included and what is not included in a drug's labeling. Once approved, all promotional material must be consistent with a drug's FDA-approved labeling. *See* 21 C.F.R. § 202.1. In fact, the FDCA and FDA regulations define "labeling" to include all hard-copy promotional material "upon" or "accompanying" the drug, including the package insert for the drug, and everything from booklets to calendars, if the material is textually related to the drug. *See* 21 U.S.C. § 321(m); 21 C.F.R. § 202.1(l)(2). The FDA regulations also expressly set forth guidelines for permissible advertising of prescription drugs. *See* 21 C.F.R. § 202.1(a)-(e)(4). In addition, the regulations explicitly define when an advertisement is false or misleading. *See id.* § 202.1(e)(5)-(7). The FDA has comprehensive statutory authority over every aspect of the safety, efficacy, labeling, marketing, advertising, and promotion of prescription drugs. *See, e.g.*, 21 U.S.C. §§ 331-334, 337; (*see also* Compl. at ¶ 52).

In light of these requirements, the Third Circuit concluded that "allowing these claims to proceed would unnecessarily frustrate the FDCA's purpose and FDA regulations, as the extent of agency involvement in regulating prescription drug advertising is extensive and specific." *Zeneca*, 499 F.3d at 251 (citing 21 C.F.R. § 202.1(e)(6)(i)-(xx) and (e)(7)(i)-(xiii)).[15] Therefore,

> [i]mplied conflict preemption of state consumer fraud laws is required in this setting because both the FDCA and FDA regulations provide specific requirements for prescription drug

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product . . . may not be marketed until an approval is effective."); 21 C.F.R. § 314.105(c) ("FDA will approve an application after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and control, and labeling . . . ."); *see also* 21 C.F.R. § 201.56 (providing that the prescribing information for a drug must be a compendium of all the information physicians require to safely and effectively prescribe drugs to treat patients); 21 C.F.R. § 314.105(b) (providing that approval of drugs is "conditioned" on use of labeling and warnings "exactly as directed" by the FDA).

[15]In addition to ads published in journals and magazines and broadcast on television, the court noted that "[a]dvertisements also come in the form of physician-directed pitches by sales representatives, computer programs, and electronic media." *Zeneca*, 499 F.3d at 245.

> advertising. Congress specifically determined that "all . . . proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). The high level of specificity in federal law and regulations with respect to prescription drug advertising is irreconcilable with general state laws that purport to govern all types of advertising. *See, e.g.*, 21 U.S.C. § 352(n); 21 C.F.R. § 314.81(b)(3). Accordingly, the plaintiffs' state consumer fraud claims are preempted.

*Id.* at 251-52.

Critical to the court's analysis was the decision by Congress to consolidate regulatory power over prescription drug advertising into a single federal agency -- the FDA. The FDA and the FTC "originally shared jurisdiction over prescription drug advertising." *Id.* at 243. In 1962, however, "regulatory authority over prescription drug advertising was transferred to the FDA." *Id.* at 149 n. 10. As the court explained it, by doing so, "Congress signaled its intent to give the FDA exclusive authority to regulate prescription drug advertising." *Id.* at 253. By the same token, "[t]o allow generalized state consumer fraud laws to dictate the parameters of false and misleading advertising in the prescription drug context would pose an undue obstacle to both Congress's and the FDA's objectives in protecting the nation's prescription drug users." *Id.*

***Preemption in this context admits of no exceptions***. There is no "safe harbor" or other exception to preemption, even for allegations of "off-label" promotion and/or misbranding. In fact, the Third Circuit rejected the *Zeneca* plaintiffs' attempt to do just that. Specifically, the plaintiffs sought leave to amend their complaint to add allegations establishing that the comparative claims at issue in the case had been *specifically rejected* by the FDA during the negotiations over the Nexium labeling and therefore constituted misbranding and/or "off-label" promotion. *See id.* at 252. The court explained that the proposed amendment was futile "because the advertisements ***are not subject to state consumer fraud law*** . . . ." *Id.* 252-53

(emphasis added). On the contrary, Congress intended "to give the FDA *exclusive authority* to regulate prescription drug advertising." *Id.* at 253 (emphasis added). Thus, whether or not a given promotional claim can be made is solely a question of federal law to be decided by a federal agency.

Recent pronouncements by the FDA further support the *Zeneca* court's finding of preemption. In a series of amicus briefs and a recently issued policy statement, the FDA expressly stated that its regulations regarding labeling and advertising preempt certain state tort claims. *See* 71 Fed. Reg. 3922, 3934 (2006); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 530-32 (E.D. Pa. 2006) (recounting history of the FDA's statements on implied preemption of state law failure to warn claims). The FDA's position is owed deference. *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (deferring to agency's interpretation of own regulations); *see also Hillsborough County, Fla. v. Automated Med. Labs.*, Inc., 471 U.S. 707, 714 (1985) (noting that statement by the FDA was "dispositive on the question of implicit intent to pre-empt"); *Colacicco*, 432 F.Supp. 2d at 530; *Tucker v. SmithKline Beecham Corp. d/b/a GlaxoSmithKline*, No. 1:04-cv-1748, 2007 WL 2726259, at *8-9 (S.D. Ind., Sept. 19, 2007).

In sum, the high level of specificity of the relevant federal statutes and regulations coupled with Congress and the FDA's explicit determination that policing the violation of any such regulations shall be the exclusive responsibility of the United States leaves no room for states to regulate prescription drug advertising and promotion through generalized consumer fraud laws.[16] Accordingly, Plaintiff's consumer fraud claims are preempted.

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[16] Even Plaintiff expressly acknowledges the importance of the federal system: "It would be impractical and unduly expensive for the Class Members to perform their own clinical studies or to assemble all known medical evidence related to OxyContin's uses. Class Members rely upon federal law obligating Defendants to provide fair and balanced information about their drug

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The Third Circuit's holding that preemption barred the plaintiff's consumer fraud claim also required the court to dismiss the plaintiffs' unjust enrichment claims. *See Zeneca*, 499 F.3d at 252 n.12. The court determined that "[b]ecause no fraud claim exists under the [Delaware Consumer Fraud Act] due to the operations of preemption, there was no deception by Zeneca cognizable in state law." *Id.* Because there was no deception, there was no unjust enrichment. *Id.* The same analysis applies with equal force here.

## IV. PLAINTIFF'S CLAIMS ARE BARRED BY THE STATUTE OF LIMITATIONS.

To determine the statute of limitations in a diversity case, a federal court must look to the conflict of laws rules of the state in which the court sits. *See Cantor Fitzgerald Inc. v. Lutnick*, 313 F.3d 704, 710 (2d Cir. 2002). Under New York's borrowing statute, the statute of limitations for claims filed by a foreign plaintiff is the shorter of either the New York statute of limitations or the statute of limitations of the foreign state where the cause of action accrued.[17] *See* N.Y. C.P.L.R. § 202.

### A. Plaintiff's Consumer Protection Claims.

Under New York law, the statute of limitations for liability created by a statute (such as consumer protection statutes) is three years. *See* N.Y. C.P.L.R. § 214(2). New Mexico applies a

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products and reasonably presume that when marketing, promoting, advertising and selling OxyContin, that such was done in compliance with Defendants' obligations under federal law." (Compl. ¶ 96.)

[17] Plaintiff alleges that its principal place of business is in New Mexico. (*See* Compl. ¶ 5.) New Mexico, therefore, is the foreign state for purposes of the statute of limitations analysis. *See Lutnick*, 313 F.3d at 710 ("New York follows 'the traditional definition of accrual - a cause of action accrues at the time and in the place of the injury. Where, as here, the 'injury is purely economic, the place of the injury usually is where the plaintiff resides and sustains the economic impact of the loss.'") (internal citation omitted) (citing *Global Fin. Corp. v. Triarc Corp.*, 715 N.E.2d 482, 485 (N.Y. 1999)).

four-year statute of limitations to consumer protection laws. *See* N.M. Stat. Ann. § 37-1-4; *see also Nance v. L.J. Dolloff Assocs., Inc.*, 126 P.3d 1215, 1220 (N.M. Ct. App. 2005). New York's shorter three-year statute of limitations therefore governs Plaintiff's consumer protection claims. *See Gaidon v. Guardian Life Ins. Co. of Am.*, 750 N.E.2d 1078, 1082 (N.Y. 2001); *Soskel v. Handler*, 736 N.Y.S.2d 853, 854 (N.Y. Super. Ct. 2001) (acknowledging "the three year statute of limitations for violation of Sections 349 and 350" of the New York consumer protection law); *see also Morelli v. Weider Nutrition Group, Inc.*, 712 N.Y.S.2d 551, 553 (N.Y. App. Div. 2000) (applying three-year statute of limitations to New York consumer protection law claim for defendants' alleged misrepresentations relating to nutritional content of food product). No discovery rule applies. *See Wender v. Gilberg Agency*, 716 N.Y.S.2d 40, 41-21 (N.Y. App. Div. 2000). Thus, any of Plaintiff's claims that arose prior to three years of filing the Complaint (Aug. 1, 2007) are barred.[18]

This is fatal to Plaintiff's consumer protection claim. As is clear on the face of the Complaint, the alleged misconduct that forms the basis for Plaintiff's claim occurred more than six years before this case was filed. (*See, e.g.,* Compl. ¶¶ 21-24, 32, 34, 37, 52 (noting that Purdue pled guilty to a violation of 21 U.S.C. §§ 331 for actions occurring "'between January 1996 and June 30, 2001'").) As the Complaint also makes clear, by the summer of 2001, the alleged misconduct was widely known and easily accessible to any who cared to learn of it. In fact, by that time, a number of government agencies had taken very public actions concerning the

[18] Plaintiff filed an action based on the same alleged misconduct at issue here on January 17, 2006. *See New Mexico Fund v. Purdue*, No. 06CV0354 (S.D.N.Y. Jan. 17, 2006). Because (like this case) that case was based on pre-2001 conduct, it was untimely as filed. In any event, Plaintiff voluntarily dismissed the case three months later, on April 27, 2006. Thus, at best, the earlier-filed case would have tolled the statute of limitations for three months and ten days. This does nothing to help Plaintiff.

marketing, labeling, and promotion of OxyContin. (*See, e.g., id.* ¶ 45 (DEA "officials asked Purdue to limit distribution of OxyContin to doctors who managed pain."); *id.* ¶ 46 ("FDA required that its strongest warning . . . be placed on OxyContin's label and package insert, the so-called 'black box warning' . . . ."); *id.* ¶ 47 ("T]he Connecticut Attorney General's Office called for Purdue to take action by completely overhauling and reforming its marketing and distribution of OxyContin . . ."). Moreover, by this time, Plaintiffs' *own counsel* in this case had filed an essentially identical complaint on behalf of another third-party payor. (*See Allied Services Division Welfare Fund v. Purdue Pharma*, No. 2001-L-1458 (Ill. Sept. 17, 2001) (Attached as Ex. B to the Peterson Declaration).) Indeed, huge sections of the Complaint here are copied almost verbatim from the earlier-filed case. (*Compare, e.g., id.* ¶¶ 15-31 *to* Compl. ¶¶ 12-30.)

In apparent recognition of the significant obstacle presented by the statute of limitations here, Plaintiff "submits that Defendants' deceptive and aggressive marketing tactics continued." (Complaint ¶ 61.) As "evidence" of the alleged continuing misconduct, Plaintiff cites only two examples: (1) a Warning Letter issued to Purdue by the FDA in *January 2003*;[19] and (2) Purdue's "*early 2003*" distribution of a "branded goniometer -- a range and motion measurement guide" -- which was mentioned in the widely publicized General Accounting Office report issued in *December 2003*. As a threshold matter, the mere "continuation" of already widely public misconduct does nothing to toll the statute of limitations. *See LaMure v. Peters*, 924 P.2d 1379, 1383-84 (N.M. App. 1996) (rejecting plaintiffs' argument that continuing nature of injury should extend statute of limitations, and holding that statute of limitations began to run when plaintiffs

[19] The FDA's Warning Letter pertains to a single ad published in the October 2, 2002 and November 13, 2002 editions of the Journal of the American Medical Association ("JAMA"). Although Purdue disagreed with the FDA's interpretation of the advertisement, Purdue voluntarily agreed to discontinue the advertisements and published "corrective" advertising in both JAMA and a number of other medical journals.

knew or should have known of injury); *see also Tiberi v. Cigna Corp.*, 89 F.3d 1423, 1430-31 (10th Cir. 1996) (recognizing that statute of limitations begins to run when an injury is discoverable, and finding that "continuing wrong doctrine" may apply in the case because defendant promised to compensate plaintiff for loss and plaintiff had exclusive relationship with defendant). In any event, to the extent these "examples" have any relevance, they do nothing but affirm that the conduct at issue in this case could be easily ascertained by anyone who cared to learn of it years before this case was filed.[20]

Finally, in an attempt to rescue its stale claim, Plaintiff invokes (in a single sentence) the so-called "fraudulent concealment" doctrine: "As a result of the Defendant's fraudulent concealment, the applicable statute of limitations have been tolled as to all claims." (Compl. at ¶ 76.) This is nowhere near sufficient. Plaintiff makes no attempt to plead (even in conclusory fashion) the required elements of fraudulent concealment, *see, e.g., New York v. Hendrickson Bros., Inc.*, 840 F.2d 1065, 1083 (2d Cir. 1988), let alone to satisfy the heightened pleading requirements of Rule 9(b), which apply with full force to claims of "fraudulent concealment." *See, e.g.*, *Armstrong v. McAlpin*, 699 F.2d 79, 88 (2d Cir. 1983) (rejecting fraudulent concealment claim where "Appellants' generalized and conclusory allegations of fraudulent concealment do not satisfy the requirements of Fed. R. Civ. P. 9(b)"); *Abercrombie v. Andrew College*, 438 F. Supp. 2d 243, 266 (S.D.N.Y. 2006) ("any claim that a defendant's fraudulent concealment bars invocation of a statute of limitations defense must comport with Fed. R. Civ. P. 9(b) in that it must be sufficiently particularized"). Moreover, as shown above (and

[20] The Court can also take judicial notice of the fact that by the end of 2001 over 2300 articles concerning OxyContin had appeared in newspapers across the country (Westlaw search of "OxyContin" in "Allwires" with a date restriction of 2001). Moreover, the Court can take judicial notice of the fact that, by August 2003, ***over 300*** individual and putative class actions raising allegations similar to those at issue here. **[Affidavit of Paulette Peterson at ¶ 2.]**

demonstrated by Plaintiffs' own counsel's filing of the *Allied Services* case), even the most minimal investigation of widely-published changes conducted in 2001 would have yielded a set of allegations indistinguishable from those pleaded here. In short, there is simply no getting around the statute of limitations here.

**B. Plaintiff's Unjust Enrichment Claim.**

Like its UPA claims, Plaintiff's unjust enrichment claim is barred by the statute of limitations. Under New York law, the statute of limitations for unjust enrichment claims is six years. *See* N.Y. C.P.L.R. § 213(1). Under New Mexico, the applicable statute of limitations is four years. *See* N.M. Stat. Ann. § 37-1-4 (applying the four-year statute of limitations to "all other actions not herein otherwise provided for and specified").[21] As the shorter of the two, New Mexico's statute applies.

Although New Mexico applies the discovery rule to certain causes of action, *see* N.M. Stat. Ann. § 37-1-7, such a rule does not help Plaintiff here. As shown above, Plaintiff either knew or should have known of its putative claims by at least September 17, 2001 -- the date its own counsel filed the *Allied Services* case. *See supra* Section IV(A). Nor does the fraudulent concealment doctrine apply. *See id.*; *see also Continental Potash v. Freeport-McMoran, Inc.*, 858 P.2d 66, 74 (N.M. 1993) ("The party must plead the circumstances giving rise to estoppel with particularity. Bald allegations of concealment are not sufficient to make out a case of fraudulent concealment."). Thus, because Plaintiff's "unjust enrichment" claim accrued well before August 2003, it is barred by the statute of limitations.

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[21] Purdue is not aware of any New Mexico court that has applied this provision to an unjust enrichment claim. The four-year catch-all statute, however, undoubtedly applies to claims of unjust enrichment because the New Mexico statute does not explicitly provide for a limitation on bringing unjust enrichment claims.

**C. Plaintiff's RICO Claims Are Barred By The Statute Of Limitations.**

As was true of its UPA and unjust enrichment claims (and for the same reasons), Plaintiff's RICO claims are time-barred. Civil RICO claims are governed by a four year statute of limitations. *See Agency Holding Corp. v. Malley-Duff & Assocs., Inc.*, 483 U.S. 143, 156 (1987). A plaintiff must bring an action for a civil RICO violation within four years from the time the plaintiff "discovered or should have discovered the injury." *Bankers Trust Co. v. Rhoades*, 859 F.2d 1096, 1102-03 (2d Cir. 1988). Under the separate accrual rule, however, "a new claim accrues and the four-year limitation period begins anew each time a plaintiff discovers or should have discovered a new and independent injury." *In re Merrill Lynch Ltd P'ships Litig.*, 154 F.3d 56, 59 (2d Cir. 1998). As the Second Circuit has acknowledged, "[a] necessary corollary of the separate accrual rule is that plaintiff may only recover for injuries discovered or discoverable within four years of the time suit is brought." *Bingham v. Zolt*, 66 F.3d 553, 560 (2d Cir. 1995). Taken together, (1) a plaintiff must bring a lawsuit for an injury resulting from a RICO violation within four years from the time the plaintiff should have been aware of its injury, or (2) a plaintiff may recover for new and independent injuries that occurred within the four years from the filing of its lawsuit even though other injuries may be barred.

Here, as shown above, Plaintiff should have been aware of any alleged injury by least September 17, 2001. *See supra* Section IV(A). Indeed, exercise of even the most minimal investigation at this time would have revealed its putative causes of action. *See id.; see also In re Merrill Lynch Ltd P'ships Litig.*, 154 F.3d at 60 (finding that the plaintiffs failed to plead fraudulent concealment of their cause of action when plaintiffs did not allege that they exercised due diligence to ascertain any cause of action against the defendant). The only other alleged acts of misconduct mentioned in the Complaint occurred in late 2002/early 2003. *See supra* Section

IV(A). These events are too remote in time to permit Plaintiff to invoke the separate accrual rule. Accordingly, the statute of limitations bars Plaintiff's RICO claim their entirety.

## V. PLAINTIFF FAILS TO STATE A CLAIM FOR UNJUST ENRICHMENT.

New York choice of laws rules mandate that Connecticut's substantive laws apply to Plaintiff's claim for unjust enrichment because Connecticut -- the site of Purdue's corporate headquarters -- is the state where the alleged "benefit" or "enrichment" was allegedly received. *See In re Rezulin Liab. Litig.*, 392 F. Supp. 2d at 618-19; (Compl. at ¶¶ 6-9, 14-16). Under Connecticut law, Plaintiff's claim for unjust enrichment fails because there is no allegation that Plaintiff actually paid Purdue directly or interacted with Purdue in any way. There is only the suggestion that Purdue benefited because, in Plaintiff's satisfaction of its obligations to its members, Purdue's drugs happened to be purchased. Such tenuous inferences do not support a claim for unjust enrichment. *See Granito v. Int'l Bus. Machs.*, No. X07CV020080440S, 2003 WL 1963161, at *2 (Conn. Super., Apr. 16, 2003) ("There is no allegation that the plaintiff or members of the proposed class paid defendant directly for the [product] as opposed to paying third party retailers, middlemen, or computer manufacturers. The fact that, ultimately, the defendant may have received payment from someone for the [product] is insufficient to establish a right to recover profits by this plaintiff."); *see also In re Rezulin Prod. Liab. Litig.*, 392 F. Supp. 2d 597, 619-21 (S.D.N.Y. 2005) (interpreting New Jersey law and rejecting health benefit providers' claim for unjust enrichment based on the absence of sufficient relationship between plaintiffs and the defendant drug manufacturer); *but cf. Zeigler v. Sony Corp. of America*, 849 A.2d 19, 25 (Conn. Super. 2004) (disagreeing with holding in *Granito* that plaintiff must confer a direct benefit when plaintiff alleges that product is defective).

The Plaintiff's unjust enrichment claim also fails because Plaintiff continues to reimburse its members for OxyContin even today notwithstanding its knowledge of Purdue's alleged misconduct. As a number of courts have recognized, where as here, "the plaintiff, acting with knowledge of the facts, pays for the product and continues to use the product, there is no unjust enrichment and recovery is barred." *Whalen v. Pfizer, Inc.*, No. 600125/05, 2005 WL 2875291, at 5 (N.Y. Sup. Ct. 2005); *see also Prohias v. Pfizer, Inc.*, 485 F.Supp. 2d 1329, 1334-35 (S.D.Fla. 2007) (unjust enrichment claim against pharmaceutical company defendant failed as a matter of law where, as here, the plaintiffs "*still pay for* Lipitor notwithstanding their knowledge of its alleged lack of benefits" (emphasis in original)).

## CONCLUSION

For the foregoing reasons, Purdue respectfully requests that the Court grant its motion and dismiss Plaintiff's Complaint in its entirety and with prejudice.

s/Donald I Strauber

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